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| FORM PTO-1449 (Rev. 2-32) | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTY. DOCKET NO. 31927-CIP2 | SERIAL NO. 10/635,048 |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) | | APPLICANT: Jallal Messadek | | | |
| | | FILING DATE: August 4, 2003 | | GROUP: 1614 | CONF. NO: 6961 |

U.S. PATENT DOCUMENTS

| EXAM. INITIAL | DOCUMENT NUMBER | INVENTOR NAME | CLASS | SUB-CLASS | ISSUE DATE (PATENT); PUBLICATION DATE (PUBLISHED APPLICATION); OR FILING DATE (NON-PUBLISHED APPLICATION) |
|---------------|-----------------|-----------------|-------|-----------|---|
| /T.B./ | 6 8 5 5 7 3 4 | Messadek | | | February 15, 2005 |
| /T.B./ | 2005/0233877 | Messadek et al. | | | October 19, 2006 |
| /T.B./ | 5 7 1 6 9 4 1 | Rabinoff | | | February 10, 1998 |
| /T.B./ | 2002/0183380 | Hunter | | | December 5, 2002 |

FOREIGN PATENT DOCUMENTS

| | DOCUMENT NUMBER | PUBLICATION DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|--------|-------------------------|------------------|---------|-------|-----------|-----------------|
| /T.B./ | FR 2590M (927 734) | 12 Mars 1963 | France | | | YES X |
| /T.B./ | WO 02/062322 | 15 August 2002 | WIPO | | | X |
| /T.B./ | WO 02/00213 | 3 January 2002 | WIPO | | | X |
| /T.B./ | WO 2004/032916 | 22 April 2004 | WIPO | | | X |
| /T.B./ | WO 97/38686 | 23 October 1997 | WIPO | | | X |
| /T.B./ | FR 70.47549 (2.119.889) | 31 Decembre 1970 | France | | | X (google only) |

OTHER DOCUMENTS (Including Publisher, Author, Title, Relevant Pages, and Date and Place of Publication)

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| /T.B./ | | McGregor et al, "A Controlled Trial of the Effect of Folate Supplements on Homocysteine, Lipids and Hemorheology in End-Stage Renal Disease," <i>Nephron</i> , Vol. 85, No. 3, 2000, 215-220 |
| /T.B./ | | Gurfinkel et al., "Fast platelet suppression by lysine acetylsalicylate in chronic stable coronary patients. Potential clinical impact over regular aspirin for coronary syndromes," <i>Clin. Cardiol.</i> , 2000 Sep;23(9):697-700. |
| /T.B./ | | Klasing et al., "Dietary Betaine Increases Intraepithelial Lymphocytes in the Duodenum of Coccidia-Infected Chicks and Increases Functional Properties of Phagocytes," 2002, <i>The American Society for Nutritional Sciences, J. Nutr.</i> 132:2274-2282, 2002 |
| /T.B./ | | Schmidt et al., "Total nitric oxide production is low in patients with chronic renal disease," <i>Kidney International</i> , 2000, 58, 1261-1266 |
| /T.B./ | | Letter Regarding Dietary Supplement Health Claim for Folic Acid, Vitamin B6, and Vitamin B12 and Vascular Disease (Docket No. 99P-3029), to Jonathan W. Emord of Emord & Associates, PC, from Christine J. Lewis of the FDA, November 28, 2000 |
| /T.B./ | | Malinow, "Plasma homocyst(e)ine and arterial occlusive diseases: a mini-review," <i>Clin. Chem.</i> , 1995 Jan;41(1):173-6. |
| /T.B./ | | al Awami et al., "Homocysteine levels in patients with Raynaud's phenomenon," <i>Vasa</i> , 2002 May; 31(2): 87-90 |
| /T.B./ | | Stammer et al., "The prevalence of hyperhomocysteinemia in thromboangiitis obliterans. Does homocysteine play a role pathogenetically?" <i>Dtsch Med Wochenschr</i> , 1996 Nov 15;101(45):1417-23. |

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance. Initial if reference considered important with reason for importance in conformance with MPEP 609. /T.B./

ALL PREFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.B./

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| /T.B./ | 2002/0065320 | Messadek | | | May 30,2002 |
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FOREIGN PATENT DOCUMENTS

| | DOCUMENT NUMBER | PUBLICATION DATE | COUNTRY | CLASS | SUB- CLASS | TRANSLATION |
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| /T.B./ | WO 2004/049095 | 10 June 2004 | WIPO | | | X |
| /T.B./ | WO 01/56609 | 9 August 2001 | WIPO | | | X (ab- stract only) |
| /T.B./ | WO 02/47493 | 20 June 2002 | WIPO | | | X |
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Relevant Pages, and Date and Place of Publication)**

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| /T.B./ | | McCarty, "Co-administration of equimolar doses of betaine may alleviate the hepatotoxic risk associated with niacin therapy," Med-Hypothesis, 2000 Sep; 55(3): 189-94 |
| /T.B./ | | Letter regarding Petition for Health Claim: Folic Acid, Vitamin B6, and Vitamin B12 Dietary Supplements and Vascular Disease [Docket No. 99P-3029], to Jonathan W. Emord & Associates from Christine J. Lewis of the FDA, February 9, 2001 |
| /T.B./ | | Birnie et al. "Antimicrobial Evaluation of N-Alkyl Betaines and N-Alkyl-N,N-Dimethylamine Oxides with Variations in Chain Length," Antimicrobial Agents and Chemotherapy, Sept., 2000, p. 2514-2517 |
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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